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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,923	04/30/2001	Patrick Kennedy	1022-11	4246

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,923	KENNEDY, PATRICK	
	Examiner	Art Unit	
	Patricia Leith	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-22,24-28 and 30-32* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-8, 10-19, 21-22, 24-28 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☑ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Finality of the previous Office Action is hereby withdrawn.

Consequently, the Amendment filed After Final on 5/21/04 is hereby entered. It is further noted that the Advisory action sent 6/02/04 inadvertently stated that the Amendment filed after final on 5/21/02 would have required a new consideration and/or search due to the additional new limitation added to claim 4 in the 5/21/04 amendment. However, this was incorrect. The limitation found in claim 4 after the 5/21/04 amendment was found in a claim which was previously searched on the merits. Because prosecution is reopened on the Instant application, The After final Amendment filed 5/21/04 is hereby entered into the case.

Claims 1-8, 10-22, 24-28 and 30-32 are pending in the application.

Claims 1-3 and 20 were previously withdrawn from further consideration as they are drawn to a non-elected invention (Paper No. 3).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-8, 10-19, 21-22, 24-28 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a carrier and a composition comprising the elements of the claims (i.e., glass, fruit shell) does not reasonably provide enablement for a composition or carrier which is able to abrade the site and circulate at least one of a toxin and venom'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state

of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

In the Instant case, the claims state 'and a carrier able to abrade the site and circulate at least one of a toxin and venom out from said site' as well as 'wherein said composition is able to abrade the site and circulate at least one of a toxin and venom out from said site'. The claims are not enabling for any of the carriers listed; i.e., emollient, beeswax or gum for example, or for any of the abrasive ingredients listed; i.e., glass or fruit shells, because Applicant has not demonstrated in the Instant specification which of these ingredients actually has these effects.

Further, there is not one working example in the Specification which clearly demonstrates that any of the claimed compositions which include abrasive ingredients and carriers such as gum or a lubricant, will actually perform commensurate in scope with the claimed invention. Absent such evidence, one must consider the guidance provided by the instant specification and the prior art of record: The carriers as listed in the claims; i.e., stone, seed shell and emollients for example, were not known in the art for circulating toxins out of a wound. What is known in the prior art about emollients for example, is that these types of suspensions are made in order to texturize liquid products for ease of topical delivery. Again, emollients are not known in the art for abrading sites of insect bites and circulating toxins and venom out from said sites. The

skilled artisan would not know how to use an emollient, or any of the other listed carriers, in the manner recited by the claims.

The state of the art is unpredictable. Applicants are stating that the composition or the carrier alone actually abrades the skin, and circulates a toxin or venom out of the site of an insect bite or sting. Therefore, even if Applicants had described any compound which would actually contact the toxin or venom produced by an insect bite or sting, the compound would then need to circulate the toxin or venom away from the site of the bite or sting. ***There are no such compounds as can be found in the prior art*** and no compounds/carriers which have been taught in the Instant specification, or even eluded to which would perform such a function. It is conceivable that there may be specific compounds known in the art for cleaving specific toxins (i.e., perhaps urea or EDTA) but these compounds will not physically leave (or circulate out) the site of the sting unless manually removed from said site by adsorption or suction as two examples.

Therefore, in light of the unpredictability in the art concerning the claimed compositions and carriers in performing the claimed functions, precludes the making and use of the claimed compositions. The skilled artisan would need to perform expensive, rigorous trial and error protocols to ascertain what carriers, if any, perform the functions as required by the claims, thus leading to undue experimentation. It is further deemed that Applicants were not in possession of such carriers at the time the Invention was made, and thus, the new limitations are deemed New Matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 6, 10, 11, 21, 22, 24, 25, 26, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (WO 99/37287).

It is noted that the claims were examined on the merits for their enabled scope, namely, a pharmaceutical/cosmetic agent.

Lee (WO 99/37287) disclosed a method for treating inflammatory skin disorders with a bioactive glass (Claim 1). Lee further disclosed the bioactive glass in combination with lotions or with additional therapeutic agents such as anesthetics and anti-inflammatory agents (claim 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 8, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (WO 99/ 37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 above.

The teachings of Lee (WO 99/37287) were discussed *supra*. Lee did not specifically teach wherein the carriers for the bioactive glass were a liquid, an aqueous pharmaceutical carrier, or a paste.

Although Lee did not specifically teach wherein the bioactive glass was formulated into an aqueous carrier, or as a paste, Lee did teach that "The bioactive glass and topical treatment can be combined in any pharmaceutically acceptable carrier to facilitate application to the skin" (p.4, lines 22-25). Therefore, because water and pastes were conventional, inert carriers for pharmaceuticals, the ordinary artisan would have had a reasonable expectation that water or pastes would have been suitable vehicles for topically applying the bioactive glass composition.

Claims 5, 12-19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (WO 99/ 37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 above, and further in view of Rubin (US 5,543,149).

The teachings of Lee (WO 99/37287) were discussed *supra.*

Although Lee taught the administration of the composition could have included agents such as benzocaine and lidocaine and topical anesthetics for relief of inflammatory conditions, Lee did not teach wherein an anti-itch enzyme was added into the composition. Lee further did not teach wherein the composition was in the form of a paste or liquid or in an aqueous pharmaceutical carrier.

Rubin (US 5,543,149) taught a method for treating insect bites with digestive enzymes such as papain and pancreatin (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating insect bites/stings. This rejection is based on the well established proposition of patent law that no invention resides in combining

old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore obvious.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

07/12/04